| FORM PTO-1390 U.S<br>OFFICE<br>(REV. 11-2000)   | S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK  | ATTORNEY'S DOCKET NUMBER<br>12480-000066/US     |  |  |  |  |  |  |
|---|---|---|--|--|--|--|--|--|
| TRANSMITTAL LETTER TO THE UNITED STATES   |   | U.S. APPLICATION NO. (If known, see 37 CFR 1.5) |  |  |  |  |  |  |
| DESIGNATED/ELECT  | ED OFFICE (DO/EO/US)  | INEW SIRPHICATION                               |  |  |  |  |  |  |
| CONCERNING A FILIN  | EXPRESS MAIL LABEL NO.  |   |  |  |  |  |  |  |
| INTERNATIONAL APPLICATION NO.   | INTERNATIONAL FILING DATE   | PRIORITY DATES CLAIMED                          |  |  |  |  |  |  |
| PCT/JP03/02601  | March 5, 2003   | March 29, 2002                                  |  |  |  |  |  |  |
| TITLE OF INVENTION THERAPEUTIC DRUG BASED ON PROTEIN HOLLOW NANOPARTICLES DISPLAYING GROWTH FACTOR, ETC.  |   |   |  |  |  |  |  |  |
| APPLICANT(S) FOR DO/EO/US<br>Shunichi KURODA, Katsuyuki TANIZAWA, Akihiko KONDO, Masakazu UEDA, Masaharu SENO and Hidehiko<br>IWABUKI   |   |   |  |  |  |  |  |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:   |   |   |  |  |  |  |  |  |
| 1. This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.   |   |   |  |  |  |  |  |  |
| 2. This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.  |   |   |  |  |  |  |  |  |
| 3. This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay   |   |   |  |  |  |  |  |  |
| examination until the expiration of   | examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39 (1). |   |  |  |  |  |  |  |
| 4. The US has been elected by the expiration of 19 months from the priority date (Article 31).  |   |   |  |  |  |  |  |  |
| 5. A copy of the International Application as filed (35 U.S.C. 371(c)(2))   |   |   |  |  |  |  |  |  |
| a. a is transmitted herewith (required only if not transmitted by the International Bureau). WO 03/082344 A1  |   |   |  |  |  |  |  |  |
| b. has been transmitted by the International Bureau.  |   |   |  |  |  |  |  |  |
| c. is not required, as the application was filed in the United States Receiving Office (RO/US).   |   |   |  |  |  |  |  |  |
| 6. An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).   |   |   |  |  |  |  |  |  |
| a. is transmitted herewith.   |   |   |  |  |  |  |  |  |
| b. has been previously submitted under 35 U.S.C. 154(d)(4)  |   |   |  |  |  |  |  |  |
| 7. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).  |   |   |  |  |  |  |  |  |
| a. are transmitted herewith (required only if not transmitted by the International Bureau).   |   |   |  |  |  |  |  |  |
| b. have been transmitted by the International Bureau.   |   |   |  |  |  |  |  |  |
|   | ver, the time limit for making such amendment   | ts has NOT expired.                             |  |  |  |  |  |  |
| d. Mave not been made and will not be made.   |   |   |  |  |  |  |  |  |
| 8. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).  |   |   |  |  |  |  |  |  |
| 9. An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).   |   |   |  |  |  |  |  |  |
| 10. An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).  |   |   |  |  |  |  |  |  |
| Items 11. to 20. below concern document(s) or information included:   |   |   |  |  |  |  |  |  |
| 11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98-1449, International Search Report (PCT/ISA/210), International Preliminary Examination Report (PCT/IPEA/409), and PTO 1449 w/ Fourteen (14) References |   |   |  |  |  |  |  |  |
| 12. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.   |   |   |  |  |  |  |  |  |
| 13. A FIRST preliminary amendment   |   |   |  |  |  |  |  |  |
| 14. A SECOND or SUBSEQUENT preliminary amendment.   |   |   |  |  |  |  |  |  |
| 15. A substitute specification.   |   |   |  |  |  |  |  |  |
| 16. A change of power of attorney and/or address letter.  |   |   |  |  |  |  |  |  |
| 17. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.   |   |   |  |  |  |  |  |  |
| 18. A second copy of the published international application under 35 U.S.C. 154(d)(4).   |   |   |  |  |  |  |  |  |
| 19. A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).   |   |   |  |  |  |  |  |  |
| 20. Other items or information:   |   |   |  |  |  |  |  |  |
| 1) Eight (8) Sheets of Formal Dra<br>2) PCT Forms (PCT/IB/304) and  |   |   |  |  |  |  |  |  |

| U.S. APPLICATION NO (if knowns see 37 G   | P117/40   | INTERNATIONAL APPLICATION NO PCT/JP03/02601 |                          |        | ATTORNEY'S DOCKET NUMBER 12480-000066/US |              |  |  |
|---|---|---|--------------------------|--------|--|--------------|--|--|
| 21. The following fees are submitted:  BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5):  |   |   |                          |        | CULATIONS                                | PTO USE ONLY |  |  |
| Neither international pa  | reliminary examination fee  |   |                          |        |  |              |  |  |
|   | h fee (37 CFR 1.445(a)(2)) point fee (37 CFR 1.445(a)(2)) point fee fee (37 CFR 1.445(a)(2)) point fee (37 CFR 1.445(a)(a)(2)) point fee (37 CFR 1.445(a)(a)(a)(a)(a)(a)(a)(a)(a)(a)(a)(a)(a)( |   | \$1,080.00               |        |  |              |  |  |
|   |   |   | Ψ1,000.00                |        |  |              |  |  |
| International prelimina USPTO but Internation   | ry examination fee (37 CFR<br>nal Search Report prepared I  | 1.482) not paid to by the EPO or JPO        | \$920.00                 |        |  |              |  |  |
| International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$770.00   |   |   |                          |        |  |              |  |  |
| International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$730.00  |   |   |                          |        |  |              |  |  |
| International prelimina   | ary examination fee (37 CFF   | 2 1 482) paid to USPTO                      |                          |        |  |              |  |  |
| International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4)   |   |   |                          | \$     | 920.00                                   |              |  |  |
| ENTER API   | PROPRIATE BASIC   | C FEE AMOUNT =                              |                          | 9      | 920.00                                   |              |  |  |
|   | or furnishing the oath or dec   |   | <u> </u>                 | \$     | 0.00                                     |              |  |  |
| · · · · · · · · · · · · · · · · · · ·   | st claimed priority date (37 (  |   | DATE                     |        |  |              |  |  |
| CLAIMS Total Claims   | NUMBER FILED<br>22 - 20 =   | NUMBER EXTRA<br>2                           | RATE<br>X <b>\$18.00</b> | \$     | 36.00                                    |              |  |  |
| Independent Claims  | 1 - 3 =   | 0   | X \$86.00                | \$     | 0.00                                     |              |  |  |
|   | ENT CLAIM(S) (if applicate  |   | + \$290.00               | \$     | 0.00                                     |              |  |  |
| TOTAL OF ABOVE CALCULATIONS =   |   |   | \$                       | 956.00 |  |              |  |  |
| Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are   |   |   |                          |        |  |              |  |  |
| reduced by 1/2.   |   |   |                          | \$     | 0.00                                     |              |  |  |
| SUBTOTAL =  |   |   |                          | \$     | 956.00                                   |              |  |  |
| Processing fee of \$130.00 for furnishing the English translation later than \[ \begin{align*} \text{20} & \begin{align*} \text{30} & \begin{align*} 30 |   |   |                          | \$     | 0.00                                     |              |  |  |
| Months from the earliest claimed priority date (37 CFR 1.492(f)).  TOTAL NATIONAL FEE =   |   |   |                          | \$     | 956.00                                   |              |  |  |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be  |   |   |                          | \$     |  |              |  |  |
| accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +   |   |   |                          |        | 40.00                                    |              |  |  |
| TOTAL FEES ENCLOSED =   |   |   |                          |        | 996.00                                   |              |  |  |
|   |   |   |                          | 1      | Amount to be:<br>refunded                | \$           |  |  |
|   |   | ·   |                          |        | charged                                  | \$           |  |  |
| a. A check in the amount of \$996.00 to cover the above fees is enclosed.   |   |   |                          |        |  |              |  |  |
| b. Please charge my Deposit Account. No. 08-0750 in the amount of \$ to cover the above fees.   |   |   |                          |        |  |              |  |  |
| A triplicate copy of this sheet is enclosed.  |   |   |                          |        |  |              |  |  |
| <ul> <li>c.  The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>08-0750</u>.</li> </ul>   |   |   |                          |        |  |              |  |  |
| NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.   |   |   |                          |        |  |              |  |  |
| Send all correspondence to: Harness, Dickey & Pierce, P.L.C – Customer No. 30593  |   |   |                          |        |  |              |  |  |
| Post Office Box 8910  |   |   |                          |        |  |              |  |  |
| Reston, Virginia 201  |   |   |                          | 0      | 20 71/                                   | <i>7</i> .   |  |  |
| Date: September 28, 2004  By  |   |   |                          |        |  |              |  |  |
| Donald J. Daley #34,313   |   |   |                          |        |  |              |  |  |
| DJD/smk   |   |   |                          |        |  | t            |  |  |